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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,733	12/21/2004	Geoffrey Phillip Dobson	36749-212211	1333

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EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	**PAPER NUMBER**
1651	

MAIL DATE	DELIVERY MODE
10/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,733	DOBSON, GEOFFREY PHILLIP	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-34 and 50-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-34 and 50-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 30-34, 50-54 are pending and are considered on the merits.

Please note that applicant's Australian priority document has not been included on the Bibliographic Data Sheet. Please request a corrected filing sheet which includes Australian foreign priority document.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 33 recites "the compound"; however, there is no antecedent basis for this recitation in the independent claim as amended.

NEW MATTER

Claims 34 and 54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The recitation of "in a concentration of between ***about*** 0.5mM to ***about*** 20mM" is an expansion of the original range of 0.5mM to 20 mM.

Claim Rejections - 35 USC § 102

Claims 30, 33, 34 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 00/56145 [BA] in light of Segal *et al.* [W].

The claims are directed to a composition comprising:
a) potassium channel opener OR an adenosine receptor agonist,
b) a local anesthetic,

c) an inhibitor of Na+/H+ membrane transport.

WO 00/56145 discloses an embodiment of a composition comprising: a potassium channel opener and an adenosine receptor agonist and an anesthetic, claim 26, for *in vitro* use (p. 4, l. 17). The potassium channel opener may be an AV blocker (claim 29). An AV blocker may be verapamil (page 6, l. 6). Verapamil also has Na+/proton transport inhibitor activity (Segal *et al.*). Thus all claimed activities are present in the composition.

The species election of a) adenosine receptor agonist and c) N-amidino-3,5-diamino-6-chloropyrazine-2-carboximide HCL dehydrate is acknowledged. The above rejection is made in order to demonstrate that the generic claim is not allowable.

Claim Rejections - 35 USC § 103

Claims 30-34, 50-54 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/56145 [BA] in combination with US 5,693,462 [AI].

The claims are directed to a composition comprising:
a) an adenosine receptor agonist,
b) a local anesthetic,
c) an inhibitor of Na+/H+ membrane transport (N-amidino-3,5-diamino-6-chloropyrazine-2-carboximide HCL dehydrate, amiloride).

WO 00/56145 discloses a composition comprising an anesthetic such as lignocaine, an adenosine receptor agonist and diazoxide as K+ channel opener to protect/preserve organs *in vitro*.

The reference is missing the inclusion of the specific compound N-amidino-3,5-diamino-6-chloropyrazine-2-carboximide HCL (amiloride).

US 5,693,462 discloses inclusion of about 1-5 μM amiloride or amiloride analog to a solution to preserve organ function (col. 5, l. 28-42). Inclusion of

amiloride in preservative solutions is effective in increasing storage time and lessening injury to the organ (col. 2, ls. 60-67, col. 3, ls. 1-3).

One of ordinary skill in the art would have been motivated at the time of invention to make this addition of amiloride to the composition of WO 00/56145 in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicant's arguments filed 1/11/08 have been fully considered but they are not persuasive. Applicants argue that WO 00/56145 does not disclose the claimed composition for use in an explanted tissue or organ. Even if this statement were accurate, intended use has little patentable weight in composition claims. Further, on page 4, line 17 of WO 00/56145 it clearly states that the "present invention is particularly advantageous in arresting, protecting and/or preserving an organ while it is intact in the body of the subject, it will be appreciated that it may also maybe used to arrest, protect and/or preserve isolated organs.". Thus, for each of these two different reasons, the argument is unpersuasive, and the two references that the examiner has combined are both therefore directed to an *ex vivo* organ preservation using the components as explained above.

Applicants argue that the addition of a Na+/H+ exchange inhibitor can be potentially unsafe and the success of such an addition cannot be predicted and that unexpected success is demonstrated in extending the viability of an isolated organ or tissue.

First, the argument directed to the danger of adding a Na+/H+ exchange inhibitor is merely the argument of counsel and is unsupported by evidence or declarations of those skilled in the art. Counsel's arguments cannot take the

place of objective evidence. In re Schulze, 145 USPQ 716 (CCPA 1965); In re Cole, 140 USPQ 230 (CCPA 1964): and especially In re Langer, 183 USPQ 288 (CCPA 1974).

Second, even if applicant has shown unexpected results, the claims are not limited to the showing. See *In re* Lindner, 173 USPQ 356 (CCPA 1972) and *In re* Grasselli, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims to the showing.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). It is applicants' burden to indicate how amendments are supported by the ORIGINAL disclosure. Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone

number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Sandra Saucier/
Primary Examiner
Art Unit 1651